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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92046037
Party	Defendant NOVATECH SA NOVATECH SA Voie Antiope, ZI ATHELIA III F-13600 LA CIOTAT FRX ,
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Submission	Reply in Support of Motion
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Date	03/29/2007
Attachments	1811-71 Reply to the Opp to Registrant's Mtn to Compel.pdf (22 pages)(1319852 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the Matter of Trademark Registration No. 3,093,389
Registered on: May 16, 2006

BRYAN CORPORATION,	§	
	§	
Petitioner,	§	
	§	
v.	§	Cancellation No. 92046037
	§	
NOVATECH SA,	§	
	§	
Registrant.	§	

REGISTRANT'S REPLY TO PETITIONER'S OPPOSITION TO REGISTRANT'S MOTION TO COMPEL RESPONSES TO REGISTRANT'S FIRST AND SECOND SET OF REQUESTS FOR PRODUCTION

Pursuant to 37 C.F.R. § 2.120(e), NOVATECH SA ("Registrant") requests an order to compel BRYAN CORPORATION ("Petitioner") to supplement production of documents responsive to Registrant's First and Second Requests for Production, and now submits this Reply to Petitioner's Opposition to Registrant's Motion to Compel.

In support of its Reply, Registrant states as follows:

1. Petitioner erroneously asserts in its Opposition to Registrant's Motion to Compel that it has not relied on approval of the STERILE TALC POWDER New Drug Applications ("NDA") filed with the Federal Drug Administration ("FDA") as its basis for obtaining an alleged common law right to such term. *See* [Petitioner's Opposition to Registrant's Motion to Compel, p. 3]. To the contrary, Petitioner explains that "the FDA not only approved, but insisted on the use of the name STERILE TALC POWDER for Petitioner's FDA approved product." *See* [Petition for Cancellation, ¶ 5]. Petitioner goes on to stress how important the role of the FDA is in determining drug names for any company. *Id.* at ¶ 6. Regardless of the semantics inherent in a discussion of whether its

Petition is "based on" FDA approval of the above-mentioned NDA, it is undeniable that Petitioner has claimed "superior common law right to use of the STERILE TALC POWDER," and that such a right was allegedly received only after FDA approval of the STERILE TALC POWDER NDA on December 15, 2003. *See id.* at ¶ 2 and 5. Therefore, Registrant requests that Petitioner produce any documents related to the filing of the NDA for its STERILE TALC POWDER drug, the acceptance of the NDA, the generic name for the drug, correspondence with the FDA regarding the drug, and all information related to the FDA's "insistence" on use of the STERILE TALC POWDER term.

2. Contrary to the statements of Petitioner, Registrant has not asserted that the Petition for Cancellation was based on the SCLEROSOL NDA approved by the FDA on December 24, 1997. *See* [Petitioner's Opposition to Registrant's Motion to Compel, p. 2]; *see generally* [Registrant's Motion to Compel]. Nonetheless, Registrant believes Petitioner cannot deny that the SCLEROSOL related documents are relevant to the claims it has made in this proceeding. Registrant has found and produced to Petitioner a few examples available from the FDA's website that show the generic name for the SCLEROSOL is "sterile talc powder." *See* [Exhibit A, SCLEROSOL Related Documents]; *see also* [Ex. 2 of Petitioner's Motion to Compel (Attachments)]. Such information contradicts statements in the Petition for Cancellation, Petitioner's interrogatory answers, and Petitioner's responses to requests for production implying that the STERILE TALC POWDER term was first used after the December 15, 2003 FDA approval of its second NDA, and that continued use of the term has given Petitioner common law trademark ownership. *See* [Petition for Cancellation, ¶¶ 2-7]. Production of such documents would admittedly be damaging to Petitioner's case, but evidence showing "sterile talc powder" is the generic name of Petitioner's SCLEROSOL drug is quite relevant in determining whether Petitioner holds an alleged common law trademark interest.

Therefore, Registrant respectfully requests the Board to compel Petitioner to produce documents related to the initial SCLEROSOL application, correspondence including the generic name of the SCLEROSOL drug, labeling requirements for the SCLEROSOL drug, specimens of the SCLEROSOL drug, and any other documents related to the generic name of the SCLEROSOL drug.

3. Finally, Registrant requests that the Board compel the production of all other documents responsive to Registrant's First and Second Sets of Requests for Production for the reasons set out in Petitioner's Motion to Compel Discovery Responses.

WHEREFORE, Registrant respectfully requests that its Motion to Compel Discovery Responses be granted and that Applicant is ordered to fully respond to Registrant's First and Second Sets of Requests for Production immediately.

Respectfully submitted,

March 29, 2007
Date

/1811-71/
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CERTIFICATE OF SERVICE

I hereby certify that Registrant's Reply to Petitioner's Opposition to Registrant's Motion to Compel Responses to Registrant's First and Second Requests for Production is being sent by first class mail on this 29th day of March 2007 to the attorney of record for Petitioner at the following address:

Daniel G. Jarcho
Andrew J. Park
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1900 K Street, N.W.
Washington, D.C. 20006
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ATTORNEYS FOR PETITIONER

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ATTORNEY FOR REGISTRANT

Our File: 1811-71

Exhibit “A”

Prescribing Information

SCLEROSOL® INTRAPLEURAL AEROSOL

(Sterile Talc Powder) NDC 63256-100-30
For Intrapleural Administration Only
Shake Well Immediately Before Using

DESCRIPTION

Sclerosol® Intrapleural Aerosol (sterile talc powder 4 g) is a sclerosing agent for intrapleural administration supplied as a single-use, pressurized spray canister with two delivery tubes of 15 cm and 25 cm in length. Each canister contains 4 g of talc, either white or off-white to light grey, asbestos-free, and brucite-free grade of talc of controlled granulometry. The composition of the talc is ≥ 95% talc as hydrated magnesium silicate. The empirical formula is $Mg_3 Si_4 O_{10} (OH)_2$ with molecular weight of 379.3. Associated naturally occurring minerals include chlorite (hydrated aluminum and magnesium silicate), dolomite (calcium and magnesium carbonite), calcite (calcium carbonate) and quartz. Talc is practically insoluble in water, and in dilute solutions of acids and alkali hydroxides. The canister and delivery tubes have been sterilized by gamma irradiation. The aerosol propellant contained in Sclerosol® Intrapleural Aerosol is dichlorodifluoromethane (CFC-12) with 26 g present per canister. The canister delivers 0.4 g of talc per second through the valve and the product contains no other excipients.

CLINICAL PHARMACOLOGY

Mechanism of Action:

The therapeutic action of talc instilled into the pleural cavity is believed to result from induction of an inflammatory reaction. This reaction promotes adherence of the visceral to the parietal pleura, obliterating the pleural space and preventing reaccumulation of pleural fluid. The extent of talc systemically absorbed after intrapleural administration has not been adequately studied. Systemic exposure could be affected by the integrity of the visceral pleura, and therefore could be increased if talc is administered immediately following lung resection or biopsy.

CLINICAL STUDIES

The data demonstrating safety and efficacy of talc in the treatment of malignant pleural effusions are derived from the published medical literature. The following four trials were prospective, randomized studies of talc vs. a concurrent control, and provide sufficient detail for evaluation, including a clear, readily determined definition of response (no fluid reaccumulation by chest roentgenogram at one month or greater) and information allowing an analysis of all patients randomized. Talc was statistically significantly superior to the control arms in evaluable patients across the studies.

REFERENCE	TREATMENT	TUMOR	RESPONSE RATE IN EVALUABLE PTS p value: Fisher's Exact*	RESPONSE RATE IN ALL PATIENTS p value: Fisher's Exact*	MINIMUM DURATION OF RESPONSE
Sorenson et al. Eur. J. Respir. Dis., 1984; 65:131	Talc slurry vs. Chest tube drainage	Variety	100% (9/9) vs. 58% (7/12) p=0.022	64% (9/14) vs. 41% (7/17) p=0.285	3 months
Fentiman et al. Eur. J. Cancer Clin. Oncol., 1986; 22:1079	Talc poudrage vs. Tetracycline solution	Breast	92% (11/12) vs. 48% (10/21) p=0.022	61% (11/18) vs. 43% (10/23) p=0.345	12 months
Fentiman et al. Cancer, 1983; 52:737	Talc poudrage vs. Mustine solution	Breast	90% (18/20) vs. 53% (9/17) p=0.023	78% (18/23) vs. 39% (9/23) p=0.016	6 months
Hamed et al. Br. J. Surg., 1989; 76:1266	Talc poudrage vs. Bleomycin solution	Breast	100% (10/10 procedures) vs. 33% (5/15 procedures) p=0.001	(unclear; results reported as procedures, not patients)	≥1 month

*p values are two-sided

In other studies, greater than 1000 patients with malignant pleural effusions have been reported (with varying degrees of detail and durations of response) to have had successful pleurodesis with talc.

INDICATIONS AND USAGE

Sclerosol® Intrapleural Aerosol, administered by aerosol during thoracoscopy or open thoracotomy, is indicated to prevent recurrence of malignant pleural effusions in symptomatic patients.

CONTRAINDICATIONS

None known.

WARNINGS

None.

PRECAUTIONS

General:

1) Future procedures. The possibility of future diagnostic and therapeutic procedures involving the hemithorax to be treated must be considered prior to administering Sclerosol® Intrapleural Aerosol. Sclerosis of the pleural space may preclude subsequent diagnostic procedures of the pleura on the treated side. Talc sclerosis may complicate or preclude future ipsilateral lung resective surgery, including pneumonectomy for transplantation purposes.

2) Use in potentially curable disease. Talc has no known antineoplastic activity and should not be used for potentially curable malignancies where systemic therapy would be more appropriate, e.g., a malignant effusion secondary to a potentially curable lymphoma.

3) Potential pulmonary complications. Acute pneumonitis or acute respiratory distress syndrome (ARDS) have rarely been reported in association with intrapleural talc administration. Whether these were causally related to talc is unclear. In none of the reported cases was talc applied thoracoscopically or by insufflation. Three of four case reports of ARDS have occurred after treatment with 10 g of talc administered via intrapleural chest tube instillation. One patient died one month post treatment and two patients recovered without further sequelae.

Intravenous administration of talc is a well-recognized cause of pulmonary hypertension and pulmonary lung parenchymal disease, but these complications have not been reported after intrapleural administration. Pulmonary diseases, e.g., silicosis or asbestosis-like diseases, chronic bronchitis, bronchogenic carcinoma, and pleural plaques have been reported in association with inhaled talc.

4) Contents under pressure. The contents of the Sclerosol® Intrapleural Aerosol (sterile talc powder) canister are under pressure. The canister must not be punctured and should not be used or stored near heat or open flame.

Drug Interactions: It is not known whether the effectiveness of a second sclerosing agent after prior talc pleurodesis would be diminished by the absorptive properties of talc.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies on the carcinogenicity of talc have been performed using non-standard designs, which prevent firm conclusions on its carcinogenicity. With single intraperitoneal administration to mice at 20 mg and observation for at least 6 months, or 4 weekly doses administered intraperitoneally at 25 mg/dose to rats with observation for at least 84 weeks, tumor incidence was not increased. In these studies, the talc and its asbestos content were not characterized. Genotoxicity was assessed in cultures of rat pleural mesothelial cells (RPMC), as unscheduled DNA syntheses (UDS) and sister chromatid exchanges (SCEs). None of the talc samples (which were asbestos free) enhanced UDS or SCEs in treated cultures. No information is available on impairment of fertility in animals by talc.

Pregnancy: Pregnancy category B. An oral administration study has been performed in the rabbit at 900 mg/kg, approximately 5-fold higher than the human dose on mg/m² basis, and has revealed no evidence of teratogenicity due to talc. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless it is clearly needed.

Pediatric Use: The safety and efficacy of Sclerosol® Intrapleural Aerosol (sterile talc powder) in pediatric patients has not been established.

Geriatric Use: The mean and median ages of patients treated with talc in the clinical studies table were 50-62 years. No analyses to specifically evaluate the safety and efficacy in the geriatric population have been reported.

ADVERSE REACTIONS

Talc administration has been described in more than 1500 patients reported in the medical literature. Patients with malignant pleural effusions were treated with talc via poudrage or slurry. In general, with respect to reported adverse experiences, it is difficult to distinguish the effects of talc from the effects of the procedure(s) associated with its administration. The most reported common adverse experiences were fever and pain. Almost all of the cases of fever, and over half of the cases of pain, were in patients who received diagnostic biopsies at the time of talc administration.

Infections: Empyema was a rare complication of talc administration and/or the procedure. Biopsies had been obtained prior to onset in over half the reported cases.

Respiratory: Rare instances of pneumonia, ARDS, dyspnea, bronchopleural fistula, hemoptysis, and pulmonary emboli have been reported.

Cardiovascular: Tachycardia, myocardial infarction, hypotension, hypovolemia, and asystolic arrest associated with surgery and/or anesthesia have been rarely reported.

Delivery Procedure: Adverse reactions due to the delivery procedure and the chest tube may include: infection at the site of thoracostomy or thoracoscopy, localized bleeding, and subcutaneous emphysema.

Chronic Toxicity: Lange et al. (Thorax 1988;43:559) reported on 114 consecutive cases of idiopathic spontaneous pneumothorax treated with talc poudrage (60 patients), or simple drainage (54 patients) via an intercostal tube. Pulmonary function tests (FEV1, VC, TLC, and RV) 22 to 35 years after treatment, showed no significant differences in the incidence of pleural changes between the two groups. Two patients treated with talc poudrage had more extensive pleural thickening with calcification. The mean total lung capacities were 83% of predicted in the talc group and 96% in the drainage only group. Fourteen patients (12 lifelong heavy smokers, 2 non-smokers) had airflow limitation (5 severe). Source and purity of the talc used was not reported. No cases of mesothelioma were reported. One case report noted the occurrence of adenocarcinoma of the chest wall two years after pleurodesis following 10 g of 1% iodized talc (administered for recurrent pneumothorax).

OVERDOSAGE

Overdosages have not been reported. (See PRECAUTIONS: 3) Potential pulmonary complications.

DOSAGE AND ADMINISTRATION

Sclerosol® Intrapleural Aerosol (sterile talc powder) is administered after adequate drainage of the effusion. It has been suggested that success of the pleurodesis is related to the completeness of the drainage of the pleural fluid, as well as full reexpansion of the lung, both of which will promote symphysis of the pleural surfaces.

The usual dosage of Sclerosol® Intrapleural Aerosol (sterile talc powder) is a single 4-8 g dose delivered intrapleurally from the spray canister (1-2 cans), which delivers talc at a rate of 0.4 g per second.

ADMINISTRATION PROCEDURE

Shake canister well before usage. Remove protective cap and securely attach actuator button with its delivery tube (either 15 cm or 25 cm) to the valve stem of canister.

Insert delivery tube through pleural trocar, taking care not to place the distal end of the delivery tube adjacent to the lung parenchyma or directly against the chest wall. While firmly holding the delivery tube and pleural trocar together in one hand, gently apply pressure to the actuator button on the canister. Sclerosol® Intrapleural Aerosol is not delivered by metered dose, but depends on the extent and duration of manual compression of the actuator button on the canister. The distal end of the delivery tube should be pointed in several different directions, while short bursts are administered in order to distribute the talc powder equally and extensively on all visceral and parietal pleural surfaces. For optimal distribution, always maintain the Sclerosol® Intrapleural Aerosol (sterile talc powder) canister in the upright position. After application, discard the canister and delivery tube. The duration of chest tube drainage following talc sclerosis is dictated by the clinical situation.

HOW SUPPLIED

NDC 63256-100-30: Sclerosol® Intrapleural Aerosol (sterile talc powder) contains 4 g of talc suspended in 26 g of inert propellant in a single-use aluminum canister. The canister is fitted with a continuous spray valve which delivers approximately 0.4 g of talc per second. This canister, attached to an actuator button, and two delivery tubes of 15 cm and 25 cm length, are supplied in a sterile, flexible plastic peel pack.

STORAGE: Warning: Contents under pressure. Do not puncture or incinerate container. Store between 59°F - 86°F (15°C - 30°C). Protect against sunlight and do not expose to a temperature above 120° F (49° C), or the canister may rupture. Avoid freezing. Shake well before using.

NOTE: The indented statement below is required by the Federal Government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFCs).

Warning: Contains CFC-12, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

Distributed by: BRYAN CORPORATION, WOBURN, MA 01801

Select Prescribe for how someone prescribing a medication such as a physician may view the product label section order. Select Prepare for how someone preparing a medication such as a pharmacist or nurse may view the sections Select Administer for how someone administering a medication such as a nurse or patient may view the sections. Please send any errors, omissions, and comments to Send Comment.

Prescribe Prepare Administer

Application	
Supplement Number	020587
Complete Label	
Formatted in PDF	SCLEROSOL INTRAPLEURAL AEROSOL
Description	
Mechanism of Action	Sclerosol Intrapleural Aerosol (sterile talc powder 4 g) is a sclerosing agent for intrapleural administration supplied as a single-use, pressurized spray canister with two delivery tubes of 15 cm and 25 cm in length. Each canister contains 4 g of talc, either white or off-white to light grey, asbestos-free, and brucite-free grade of talc of controlled granulometry. The composition of the talc is =?95% talc as hydrated magnesium silicate. The empirical formula is Mg3 Si4 O10 (OH)2 with molecular weight of 379.3. Associated naturally occurring minerals include chlorite (hydrated aluminum and magnesium silicate), dolomite (calcium and magnesium carbonite), calcite (calcium carbonate) and quartz. Talc is practically insoluble in water, and in dilute solutions of acids and alkali hydroxides. The canister and delivery tubes have been sterilized by gamma irradiation. The aerosol propellant contained in Sclerosol Intrapleural Aerosol is dichlorodifluoromethane (CFC-12) with 26 g present per canister. The canister delivers 0.4 g of talc per second through the valve and the product contains no other excipients.
Generic Drug Name	sterile talc powder
Distributor	
Distributor	BRYAN CORPORATION, WOBURN, MA 01801.
Actions	
Summary	The therapeutic action of talc instilled into the pleural cavity is believed to result from induction of an inflammatory reaction. This reaction promotes adherence of the visceral to the parietal pleura, obliterating the pleural space and preventing reaccumulation of pleural fluid. The extent of talc systemically absorbed after intrapleural administration has not been adequately studied. Systemic exposure could be affected by the integrity of the visceral pleura, and therefore could be increased if talc is administered immediately following lung resection or biopsy.
Clinical Studies	
	The data demonstrating safety and efficacy of talc in the treatment of malignant pleural effusions are derived from the published medical literature. The following four trials were prospective, randomized studies of talc vs. a concurrent control, and provide

Summary	sufficient detail for evaluation, including a clear, readily determined definition of response (no fluid reaccumulation by chest roentgenogram at one month or greater) and information allowing an analysis of all patients randomized. Talc was statistically significantly superior to the control arms in evaluable patients across the studies. (table) *p values are two-sided In other studies, greater than 1000 patients with malignant pleural effusions have been reported (with varying degrees of detail and durations of response) to have had successful pleurodesis with talc.
Indications and Usage	
Summary	Sclerosol Intrapleural Aerosol, administered by aerosol during thoracoscopy or open thoracotomy, is indicated to prevent recurrence of malignant pleural effusions in symptomatic patients.
Precautions	
Summary	1) Future procedures. The possibility of future diagnostic and therapeutic procedures involving the hemithorax to be treated must be considered prior to administering Sclerosol Intrapleural Aerosol. Sclerosis of the pleural space may preclude subsequent diagnostic procedures of the pleura on the treated side. Talc sclerosis may complicate or preclude future ipsilateral lung resective surgery, including pneumonectomy for transplantation purposes. 2) Use in potentially curable disease. Talc has no known antineoplastic activity and should not be used for potentially curable malignancies where systemic therapy would be more appropriate, e.g., a malignant effusion secondary to a potentially curable lymphoma. 3) Potential pulmonary complications. Acute pneumonitis or acute respiratory distress syndrome (ARDS) have rarely been reported in association with intrapleural talc administration. Whether these were causally related to talc is unclear. In none of the reported cases was talc applied thoracoscopically or by insufflation. Three of four case reports of ARDS have occurred after treatment with 10 g of talc administered via intrapleural chest tube instillation. One patient died one month post treatment and two patients recovered without further sequelae. Intravenous administration of talc is a well-recognized cause of pulmonary hypertension and pulmonary lung parenchymal disease, but these complications have not been reported after intrapleural administration. Pulmonary diseases, e.g., silicosis or asbestosis-like diseases, chronic bronchitis, bronchogenic carcinoma, and pleural plaques have been reported in association with inhaled talc. 4) Contents under pressure. The contents of the Sclerosol Intrapleural Aerosol (sterile talc powder) canister are under pressure. The canister must not be punctured and should not be used or stored near heat or open flame. Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies on the carcinogenicity of talc have been performed using non-standard designs, which prevent firm conclusions on its carcinogenicity. With single intraperitoneal administration to mice at 20 mg and observation for at least 6 months, or 4 weekly doses administered intraperitoneally at 25 mg/dose to rats with observation for at least 84 weeks, tumor incidence was not increased. In these studies, the talc and its asbestos content were not characterized. Genotoxicity was assessed in cultures of rat pleural mesothelial cells (RPMC), as unscheduled DNA syntheses (UDS) and sister chromatid exchanges (SCEs). None of the talc samples (which were asbestos free) enhanced UDS or SCEs in treated cultures. No information is available on impairment of fertility in animals by talc. Pregnancy: Pregnancy category B. An oral administration study has been performed in the rabbit at 900 mg/kg, approximately 5-fold higher than the human dose on mg/m2 basis, and has revealed no evidence of teratogenicity due to talc. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy

	unless it is clearly needed. Pediatric Use: The safety and efficacy of Sclerosol Intrapleural Aerosol (sterile talc powder) in pediatric patients has not been established. Geriatric Use: The mean and median ages of patients treated with talc in the clinical studies table were 50-62 years. No analyses to specifically evaluate the safety and efficacy in the geriatric population have been reported.
Drug Interactions	
Summary	Drug Interactions: It is not known whether the effectiveness of a second sclerosing agent after prior talc pleurodesis would be diminished by the absorptive properties of talc.
Adverse Reactions	
Summary	Talc administration has been described in more than 1500 patients reported in the medical literature. Patients with malignant pleural effusions were treated with talc via poudrage or slurry. In general, with respect to reported adverse experiences, it is difficult to distinguish the effects of talc from the effects of the procedure(s) associated with its administration. The most reported common adverse experiences were fever and pain. Almost all of the cases of fever, and over half of the cases of pain, were in patients who received diagnostic biopsies at the time of talc administration. Infections: Empyema was a rare complication of talc administration and/or the procedure. Biopsies had been obtained prior to onset in over half the reported cases. Respiratory: Rare instances of pneumonia, ARDS, dyspnea, bronchopleural fistula, hemoptysis, and pulmonary emboli have been reported. Cardiovascular: Tachycardia, myocardial infarction, hypotension, hypovolemia, and asystolic arrest associated with surgery and/or anesthesia have been rarely reported. Delivery Procedure: Adverse reactions due to the delivery procedure and the chest tube may include: infection at the site of thoracostomy or thoracoscopy, localized bleeding, and subcutaneous emphysema. Chronic Toxicity: Lange et al. (Thorax 1988;43:559) reported on 114 consecutive cases of idiopathic spontaneous pneumothorax treated with talc poudrage (60 patients), or simple drainage (54 patients) via an intercostal tube. Pulmonary function tests (FEV1, VC, TLC, and RV) 22 to 35 years after treatment, showed no significant differences in the incidence of pleural changes between the two groups. Two patients treated with talc poudrage had more extensive pleural thickening with calcification. The mean total lung capacities were 89% of predicted in the talc group and 96% in the drainage only group. Fourteen patients (12 lifelong heavy smokers, 2 non-smokers) had airflow limitation (5 severe). Source and purity of the talc used was not reported. No cases of mesothelioma were reported. One case report noted the occurrence of adenocarcinoma of the chest wall two years after pleurodesis following 10 g of 1% iodized talc (administered for recurrent pneumothorax).
Overdosage	
Summary	Overdosages have not been reported. (See PRECAUTIONS: 3) Potential pulmonary complications.
Dosage and Administration	
	Sclerosol Intrapleural Aerosol (sterile talc powder) is administered after adequate drainage of the effusion. It has been suggested that success of the pleurodesis is related to the completeness of the drainage of the pleural fluid, as well as full reexpansion of the lung, both of which will promote symphysis of the pleural surfaces. The usual dosage of Sclerosol Intrapleural Aerosol (sterile talc powder) is a single 4-8 g dose delivered intrapleurally from the spray canister (1-2 cans), which delivers talc at a rate of 0.4 g per second. ADMINISTRATION PROCEDURE Shake canister well before usage. Remove

Summary	protective cap and securely attach actuator button with its delivery tube (either 15 cm or 25 cm) to the valve stem of canister. Insert delivery tube through pleural trocar, taking care not to place the distal end of the delivery tube adjacent to the lung parenchyma or directly against the chest wall. While firmly holding the delivery tube and pleural trocar together in one hand, gently apply pressure to the actuator button on the canister. Sclerosol Intrapleural Aerosol is not delivered by metered dose, but depends on the extent and duration of manual compression of the actuator button on the canister. The distal end of the delivery tube should be pointed in several different directions, while short bursts are administered in order to distribute the talc powder equally and extensively on all visceral and parietal pleural surfaces. For optimal distribution, always maintain the Sclerosol Intrapleural Aerosol (sterile talc powder) canister in the upright position. After application, discard the canister and delivery tube. The duration of chest tube drainage following talc sclerosis is dictated by the clinical situation.
How Supplied	
Summary	NDC 63256-0100-30: Sclerosol Intrapleural Aerosol (sterile talc powder) contains 4 g of talc suspended in 26 g of inert propellant in a single-use aluminum canister. The canister is fitted with a continuous spray valve which delivers approximately 0.4 g of talc per second. This canister, attached to an actuator button, and two delivery tubes of 15 cm and 25 cm length, are supplied in a sterile, flexible plastic peel pack. STORAGE: Warning: Contents under pressure. Do not puncture or incinerate container. Store between 59°F - 86°F (15°C - 30°C). Protect against sunlight and do not expose to a temperature above 120° F (49° C), or the canister may rupture. Avoid freezing. Shake well before using. NOTE: The indented statement below is required by the Federal Government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFCs).
NDC	
NDC	63256-0100-30
Contact	
Contact	Toll Free: 800.343.7711 Fax: 781.935.7602 Email: sales@bryancorp.com www.bryancorp.com

Select Standard to view the conventional product label section order. Select Prescribe for how someone prescribing a medication such as a physcician may view the sections Select Prepare for how someone administering a medication such as a pharmacist or nurse may view the sections Please send any errors, omissions, and comments to Send Comment.

Standard Prescribe Prepare

Description	
Generic Drug Name	sterile talc powder
Complete Label	
Formatted in PDF	SCLEROSOL INTRAPLEURAL AEROSOL
Dosage and Administration	
Summary	Sclerosol Intrapleural Aerosol (sterile talc powder) is administered after adequate drainage of the effusion. It has been suggested that success of the pleurodesis is related to the completeness of the drainage of the pleural fluid, as well as full reexpansion of the lung, both of which will promote symphysis of the pleural surfaces. The usual dosage of Sclerosol Intrapleural Aerosol (sterile talc powder) is a single 4-8 g dose delivered intrapleurally from the spray canister (1-2 cans), which delivers talc at a rate of 0.4 g per second. ADMINISTRATION PROCEDURE Shake canister well before usage. Remove protective cap and securely attach actuator button with its delivery tube (either 15 cm or 25 cm) to the valve stem of canister. Insert delivery tube through pleural trocar, taking care not to place the distal end of the delivery tube adjacent to the lung parenchyma or directly against the chest wall. While firmly holding the delivery tube and pleural trocar together in one hand, gently apply pressure to the actuator button on the canister. Sclerosol Intrapleural Aerosol is not delivered by metered dose, but depends on the extent and duration of manual compression of the actuator button on the canister. The distal end of the delivery tube should be pointed in several different directions, while short bursts are administered in order to distribute the talc powder equally and extensively on all visceral and parietal pleural surfaces. For optimal distribution, always maintain the Sclerosol Intrapleural Aerosol (sterile talc powder) canister in the upright position. After application, discard the canister and delivery tube. The duration of chest tube drainage following talc sclerosis is dictated by the clinical situation.
How Supplied	
Summary	NDC 63256-0100-30: Sclerosol Intrapleural Aerosol (sterile talc powder) contains 4 g of talc suspended in 26 g of inert propellant in a single-use aluminum canister. The canister is fitted with a continuous spray valve which delivers approximately 0.4 g of talc per second. This canister, attached to an actuator button, and two delivery tubes of 15 cm and 25 cm length, are supplied in a sterile, flexible plastic peel pack. STORAGE: Warning: Contents under pressure. Do not puncture or incinerate container. Store between 59°F - 86°F (15°C - 30°C). Protect against sunlight and do not expose to a temperature above 120° F (49° C), or the canister may rupture. Avoid freezing. Shake well before using. NOTE: The indented statement below is required by the Federal Government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFCs).

Drug Interactions	
Summary	Drug Interactions: It is not known whether the effectiveness of a second sclerosing agent after prior talc pleurodesis would be diminished by the absorptive properties of talc.
Indications and Usage	
Summary	Sclerosol Intrapleural Aerosol, administered by aerosol during thoracoscopy or open thoracotomy, is indicated to prevent recurrence of malignant pleural effusions in symptomatic patients.
Adverse Reactions	
Summary	Talc administration has been described in more than 1500 patients reported in the medical literature. Patients with malignant pleural effusions were treated with talc via poudrage or slurry. In general, with respect to reported adverse experiences, it is difficult to distinguish the effects of talc from the effects of the procedure(s) associated with its administration. The most reported common adverse experiences were fever and pain. Almost all of the cases of fever, and over half of the cases of pain, were in patients who received diagnostic biopsies at the time of talc administration. Infections: Empyema was a rare complication of talc administration and/or the procedure. Biopsies had been obtained prior to onset in over half the reported cases. Respiratory: Rare instances of pneumonia, ARDS, dyspnea, bronchopleural fistula, hemoptysis, and pulmonary emboli have been reported. Cardiovascular: Tachycardia, myocardial infarction, hypotension, hypovolemia, and asystolic arrest associated with surgery and/or anesthesia have been rarely reported. Delivery Procedure: Adverse reactions due to the delivery procedure and the chest tube may include: infection at the site of thoracostomy or thoracoscopy, localized bleeding, and subcutaneous emphysema. Chronic Toxicity: Lange et al. (Thorax 1988;43:559) reported on 114 consecutive cases of idiopathic spontaneous pneumothorax treated with talc poudrage (60 patients), or simple drainage (54 patients) via an intercostal tube. Pulmonary function tests (FEV1, VC, TLC, and RV) 22 to 35 years after treatment, showed no significant differences in the incidence of pleural changes between the two groups. Two patients treated with talc poudrage had more extensive pleural thickening with calcification. The mean total lung capacities were 89% of predicted in the talc group and 96% in the drainage only group. Fourteen patients (12 lifelong heavy smokers, 2 non-smokers) had airflow limitation (5 severe). Source and purity of the talc used was not reported. No cases of mesothelioma were reported. One case report noted the occurrence of adenocarcinoma of the chest wall two years after pleurodesis following 10 g of 1% iodized talc (administered for recurrent pneumothorax).
Precautions	
	1) Future procedures. The possibility of future diagnostic and therapeutic procedures involving the hemithorax to be treated must be considered prior to administering Sclerosol Intrapleural Aerosol. Sclerosis of the pleural space may preclude subsequent diagnostic procedures of the pleura on the treated side. Talc sclerosis may complicate or preclude future ipsilateral lung resective surgery, including pneumonectomy for transplantation purposes. 2) Use in potentially curable disease. Talc has no known antineoplastic activity and should not be used for potentially curable malignancies where systemic therapy would be more appropriate, e.g., a malignant effusion secondary to a potentially curable lymphoma. 3) Potential pulmonary complications. Acute pneumonitis or acute respiratory distress syndrome (ARDS) have rarely been reported in association with intrapleural talc administration. Whether these were causally related to talc is

Summary	unclear. In none of the reported cases was talc applied thoracoscopically or by insufflation. Three of four case reports of ARDS have occurred after treatment with 10 g of talc administered via intrapleural chest tube instillation. One patient died one month post treatment and two patients recovered without further sequelae. Intravenous administration of talc is a well-recognized cause of pulmonary hypertension and pulmonary lung parenchymal disease, but these complications have not been reported after intrapleural administration. Pulmonary diseases, e.g., silicosis or asbestosis-like diseases, chronic bronchitis, bronchogenic carcinoma, and pleural plaques have been reported in association with inhaled talc. 4) Contents under pressure. The contents of the Sclerosol Intrapleural Aerosol (sterile talc powder) canister are under pressure. The canister must not be punctured and should not be used or stored near heat or open flame. Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies on the carcinogenicity of talc have been performed using non-standard designs, which prevent firm conclusions on its carcinogenicity. With single intraperitoneal administration to mice at 20 mg and observation for at least 6 months, or 4 weekly doses administered intraperitoneally at 25 mg/dose to rats with observation for at least 84 weeks, tumor incidence was not increased. In these studies, the talc and its asbestos content were not characterized. Genotoxicity was assessed in cultures of rat pleural mesothelial cells (RPMC), as unscheduled DNA syntheses (UDS) and sister chromatid exchanges (SCEs). None of the talc samples (which were asbestos free) enhanced UDS or SCEs in treated cultures. No information is available on impairment of fertility in animals by talc. Pregnancy: Pregnancy category B. An oral administration study has been performed in the rabbit at 900 mg/kg, approximately 5-fold higher than the human dose on mg/m2 basis, and has revealed no evidence of teratogenicity due to talc. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy unless it is clearly needed. Pediatric Use: The safety and efficacy of Sclerosol Intrapleural Aerosol (sterile talc powder) in pediatric patients has not been established. Geriatric Use: The mean and median ages of patients treated with talc in the clinical studies table were 50-62 years. No analyses to specifically evaluate the safety and efficacy in the geriatric population have been reported.
Overdosage	
Summary	Overdosages have not been reported. (See PRECAUTIONS: 3) Potential pulmonary complications.
Distributor	
Distributor	BRYAN CORPORATION, WOBURN, MA 01801.
Contact	
Contact	Toll Free: 800.343.7711 Fax: 781.935.7602 Email: sales@bryancorp.com www.bryancorp.com
NDC	
NDC	63256-0100-30
Clinical Studies	
Summary	The data demonstrating safety and efficacy of talc in the treatment of malignant pleural effusions are derived from the published medical literature. The following four trials were prospective, randomized studies of talc vs. a concurrent control, and provide sufficient detail for evaluation, including a clear, readily determined definition of response (no fluid reaccumulation by chest roentgenogram at one month or greater) and

	information allowing an analysis of all patients randomized. Talc was statistically significantly superior to the control arms in evaluable patients across the studies. (table) *p values are two-sided In other studies, greater than 1000 patients with malignant pleural effusions have been reported (with varying degrees of detail and durations of response) to have had successful pleurodesis with talc.
Actions	
Summary	The therapeutic action of talc instilled into the pleural cavity is believed to result from induction of an inflammatory reaction. This reaction promotes adherence of the visceral to the parietal pleura, obliterating the pleural space and preventing reaccumulation of pleural fluid. The extent of talc systemically absorbed after intrapleural administration has not been adequately studied. Systemic exposure could be affected by the integrity of the visceral pleura, and therefore could be increased if talc is administered immediately following lung resection or biopsy.
Description	
Mechanism of Action	Sclerosol Intrapleural Aerosol (sterile talc powder 4 g) is a sclerosing agent for intrapleural administration supplied as a single-use, pressurized spray canister with two delivery tubes of 15 cm and 25 cm in length. Each canister contains 4 g of talc, either white or off-white to light grey, asbestos-free, and brucite-free grade of talc of controlled granulometry. The composition of the talc is =?95% talc as hydrated magnesium silicate. The empirical formula is Mg3 Si4 O10 (OH)2 with molecular weight of 379.3. Associated naturally occurring minerals include chlorite (hydrated aluminum and magnesium silicate), dolomite (calcium and magnesium carbonite), calcite (calcium carbonate) and quartz. Talc is practically insoluble in water, and in dilute solutions of acids and alkali hydroxides. The canister and delivery tubes have been sterilized by gamma irradiation. The aerosol propellant contained in Sclerosol Intrapleural Aerosol is dichlorodifluoromethane (CFC-12) with 26 g present per canister. The canister delivers 0.4 g of talc per second through the valve and the product contains no other excipients.
Application	
Supplement Number	020587

Select Standard to view the conventional product label section order. Select Prescribe for how someone prescribing a medication such as a physcician may view the sections Select Administer for how someone administering a medication such as a nurse or patient may view the sections Please send any errors, omissions, and comments to Send Comment.

Standard Prescribe Administer

Description	
Generic Drug Name	sterile talc powder
Complete Label	
Formatted in PDF	SCLEROSOL INTRAPLEURAL AEROSOL
NDC	
NDC	63256-0100-30
How Supplied	
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Summary	Sclerosol Intrapleural Aerosol (sterile talc powder) is administered after adequate drainage of the effusion. It has been suggested that success of the pleurodesis is related to the completeness of the drainage of the pleural fluid, as well as full reexpansion of the lung, both of which will promote symphysis of the pleural surfaces. The usual dosage of Sclerosol Intrapleural Aerosol (sterile talc powder) is a single 4-8 g dose delivered intrapleurally from the spray canister (1-2 cans), which delivers talc at a rate of 0.4 g per second. ADMINISTRATION PROCEDURE Shake canister well before usage. Remove protective cap and securely attach actuator button with its delivery tube (either 15 cm or 25 cm) to the valve stem of canister. Insert delivery tube through pleural trocar, taking care not to place the distal end of the delivery tube adjacent to the lung parenchyma or directly against the chest wall. While firmly holding the delivery tube and pleural trocar together in one hand, gently apply pressure to the actuator button on the canister. Sclerosol Intrapleural Aerosol is not delivered by metered dose, but depends on the extent and duration of manual compression of the actuator button on the canister. The distal end of the delivery tube should be pointed in several different directions, while short bursts are administered in order to distribute the talc powder equally and extensively on all visceral and parietal pleural surfaces. For optimal distribution, always maintain the Sclerosol Intrapleural Aerosol (sterile talc powder) canister in the upright

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Contact	
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Summary	The therapeutic action of talc instilled into the pleural cavity is believed to result from induction of an inflammatory reaction. This reaction promotes adherence of the visceral to the parietal pleura, obliterating the pleural space and preventing reaccumulation of pleural fluid. The extent of talc systemically absorbed after intrapleural administration has not been adequately studied. Systemic exposure could be affected by the integrity of the visceral pleura, and therefore could be increased if talc is administered immediately following lung resection or biopsy.

Description	
Mechanism of Action	Sclerosol Intrapleural Aerosol (sterile talc powder 4 g) is a sclerosing agent for intrapleural administration supplied as a single-use, pressurized spray canister with two delivery tubes of 15 cm and 25 cm in length. Each canister contains 4 g of talc, either white or off-white to light grey, asbestos-free, and brucite-free grade of talc of controlled granulometry. The composition of the talc is =?95% talc as hydrated magnesium silicate. The empirical formula is Mg3 Si4 O10 (OH)2 with molecular weight of 379.3. Associated naturally occurring minerals include chlorite (hydrated aluminum and magnesium silicate), dolomite (calcium and magnesium carbonite), calcite (calcium carbonate) and quartz. Talc is practically insoluble in water, and in dilute solutions of acids and alkali hydroxides. The canister and delivery tubes have been sterilized by gamma irradiation. The aerosol propellant contained in Sclerosol Intrapleural Aerosol is dichlorodifluoromethane (CFC-12) with 26 g present per canister. The canister delivers 0.4 g of talc per second through the valve and the product contains no other excipients.
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Summary	The data demonstrating safety and efficacy of talc in the treatment of malignant pleural effusions are derived from the published medical literature. The following four trials were prospective, randomized studies of talc vs. a concurrent control, and provide sufficient detail for evaluation, including a clear, readily determined definition of response (no fluid reaccumulation by chest roentgenogram at one month or greater) and information allowing an analysis of all patients randomized. Talc was statistically significantly superior to the control arms in evaluable patients across the studies. (table) *p values are two-sided In other studies, greater than 1000 patients with malignant pleural effusions have been reported (with varying degrees of detail and durations of response) to have had successful pleurodesis with talc.
Application	
Supplement Number	020587

Select Standard to view the conventional product label section order. Select Prepare for how someone preparing a medication such as a pharmacist or nurse may view the sections Select Administer for how someone administering a medication such as a nurse or patient may view the sections Please send any errors, omissions, and comments to Send Comment.

Standard Prepare Administer

Description	
Generic Drug Name	sterile talc powder
Complete Label	
Formatted in PDF	SCLEROSOL INTRAPLEURAL AEROSOL
Indications and Usage	
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NDC	
NDC	63256-0100-30
Contact	
Contact	Toll Free: 800.343.7711 Fax: 781.935.7602 Email: sales@bryancorp.com www.bryancorp.com
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Supplement Number	020587